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Descriptive Statistical Evaluation of the Standard Days Method of Family Planning

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Abstract

The Standard Days Method (SDM) is a method of family planning that assumes ovulation to be close to the midpoint of the menstrual cycle; fertility falls between days 8 and 19; and is most effective for cycle lengths between twenty-six and thirty-two days. The purpose of this study was to evaluate the assumptions of the SDM with a new data set of 714 menstrual cycles produced by 131 women (mean age twenty-nine) who tracked their fertility with an electronic fertility monitor that measured urinary estrogen and luteinizing hormone (LH). The LH peak was used to estimate the day of ovulation (EDO) and the six-day fertile window. Results indicated the majority (80 percent) of menstrual cycles had EDOs within three days of the midpoint of the cycle (86 percent with cycle lengths between twenty-six and thirty-two days). Approximately 22.5 percent (172) of the cycles had fertile window days outside of

days 8 to 19, 10.2 percent (78) before, and 12.1 percent (92) after. However, there is a low probability of pregnancy when women experience short cycles and the early days of the fertile window are outside of days 8 through 19. We concluded assumptions of the SDM outside of the fertile window with long cycles could be problematic. However, the SDM is valid for women who have most cycles within the twenty-six to thirty-two day range.

Introduction

A simple new fertility-awareness-based system of family planning, called the Standard Days Method (SDM) was developed at Georgetown University Institute for Reproductive Health.¹ Users of the SDM are instructed to avoid intercourse on days 8 through 19 of the menstrual cycle if they do not want to become pregnant. The method is most effective for women with cycles between twenty-six and thirty-two days long. A recent extended use efficacy of the SDM over two years with participants in six developing countries yielded pregnancy rates comparable to hormonal contraception.²

An analysis of the theoretical efficacy of the SDM and a clinical efficacy trial of the method to avoid pregnancy showed that the SDM is highly effective when used according to instructions, with a correct use failure rate of less than 5 out of 100 per twelve months of use.³ Correct SDM use involved avoiding intercourse on days 8 through 19. SDM users are screened to determine appropriate cycle length prior to initiation of the method. A user who has two cycles out of the twenty-six to thirty-two day range within twelve month is advised that the method may no longer be appropriate for her.⁴

The fixed-day algorithm for the SDM is based on statistical evidence that ovulation occurs around the middle of the cycle for menstrual cycles that have lengths between twenty-six and thirty-two days.⁵ Theoretically, the SDM will be most effective when the day of ovulation falls close to the center of the menstrual cycle. However, current textbooks and existing guidelines for calendar-based methods of family planning suggest that ovulation occurs around fourteen days before the end of the menstrual cycle.⁶ Older calendar-based methods that rely on menstrual cycle length become unusable when menstrual cycles vary by more than seven days in length.⁷

Another assumption of the SDM is that the actual days of fertility fall within days 8 and 19 for menstrual cycle lengths between twenty-six and thirty-two days. The SDM overestimates the actual fertile phase within a prescribed range of cycle lengths. Therefore, for the SDM to be effective, the actual fertile phase of the menstrual cycle should not fall outside of days 8 through 19 too frequently. The fertile phase of the menstrual cycle is approximately six days, that is, the day of ovulation and the five days before.⁸ The most fertile of those six days are the two days before ovulation.⁹

The purpose of this study was to statistically evaluate the assumptions of the SDM with a new data set of menstrual cycle parameters that includes biological markers for the beginning and end of the fertile window. For menstrual cycles that potentially meet the criteria for use of the SDM, the specific research questions that were addressed are 1) in what percentage of menstrual cycles does the estimated day of ovulation (EDO) fall within one to three days of the midpoint of the menstrual cycle? And 2) In what percentage of menstrual cycles does at least part of the six-day fertile window fall outside of the eight to nineteen day range?

Methods

Design

This study was a retrospective descriptive analysis of the SDM by use of a new menstrual cycle data set. The data set was generated by 165 women who participated in a twelve-month efficacy study of the use of an electronic fertility monitor plus cervical mucus monitoring as a means of avoiding pregnancy.

Sample

The 165 women participants were solicited by health professionals from five clinical sites in four cities (Atlanta, Madison-Wisconsin, Milwaukee, and Saint Louis) when they sought instructions on how to avoid pregnancy with a natural method of family planning. The participants for the effectiveness study met the criteria of being between the ages of twenty-one and forty-four; had menstrual cycles within the range of twenty-one to forty-two days; had not used depot medroxyprogesterone acetate (DMPA) over the past twelve months; had no history of oral or subdermal contraceptives for the past three months; if post-breastfeeding, had experienced at least three menstrual cycles past weaning; and had no known fertility problems. The effectiveness study and the retrospective data analysis for this study received internal review board approval from the Marquette University Office of Research Compliance.

Procedure

The 165 participants were taught how to monitor their fertility by observing and charting their daily cervical mucus observations and by use of an electronic hormonal fertility monitor. The participants recorded their cervical mucus observations, the days of their menstrual flow, the length of the cycle, and the information they received from the fertility monitor on a fertility chart. The fertility charts were collected and copied by a designated coordinator at each of the five clinical sites. All data charts were sent to the Marquette University Institute for Natural Family Planning, and information from each chart was entered into a data set. The 165 participants produced 1,335 menstrual cycles data charts of which 1,181 (88 percent) had usable and complete data.

For the current study, participants (of the original 165) were included if they had three or more menstrual cycles of data and were classified by the health professional who entered them into the effectiveness study to be in regular cycles (i.e., cycle range of twenty-five to thirty-five days). Although the original efficacy study included women participants with cycle lengths between twenty-one and forty-two days, all participants were placed in a reproductive category at the first month follow-up based on cycle length (and pregnancy status) that included short, long, and regular cycles. The definition of regular cycles used for this data set (twenty-five to thirty-five days) is more generous in menstrual cycle length than the twenty-six to thirty-two day requirement for use of the SDM. In an attempt to be true to the algorithm of the SDM, menstrual cycles were eliminated in the data set when a given participant had a second cycle that was shorter than twenty-six or longer than thirty-two days in length.

Measurement

The Clearblue Easy Fertility Monitor (Unipath, Ltd., Bedford, England) was used by all of the participants to monitor their fertility.¹⁰ The Clearblue Monitor is a handheld electronic device that was designed to read test strips with antibodies for estrogen and LH. The monitor provides the user with a

daily reading of low, high, or peak fertility. The high reading of the monitor indicates the rising level of urinary estrone-3-gluconuride (E3G) and the peak reading indicates the surge in urinary LH. Product testing has shown the Clearblue Monitor to be 98.8 percent accurate in detecting the LH surge. The Clearblue Monitor detected the LH surge in 169 of 171 cycles from eighty-eight women, in agreement with a quantitative radioimmunoassay for LH.¹¹

Definitions

Estimated Day of Ovulation (EDO). For the purpose of this study, the EDO was the second peak day on the Clearblue Monitor. The Clearblue Monitor automatically provides two peak days when the urinary threshold of LH is reached. LH in the urine has been found to be 100 percent efficient in identifying ovulation when compared to transvaginal ultrasound.¹² A recent study utilizing serial ultrasound to determine the day of ovulation showed that ovulation occurred greater than 91 percent of the time during the two peak days of the Clearblue monitor.¹³ Thus, the detection of LH in the urine by the monitor is a good reference point for the EDO.

Fertile Window. For this study, the fertile window was estimated to be the six-day interval that ends with the second peak day reading determined by the Clearblue Monitor, i.e., the EDO and the five days before.

Data Analysis

The nineteenth version of the Statistical Package for Social Scientists was utilized to determine means, medians, standard deviations, ranges, frequencies, and percentages of the listed parameters of the menstrual cycle. Appropriate graphs and tables were applied to the statistical parameters. The distance of the EDO from the midpoint of the cycle was determined by subtracting the length of the menstrual cycle from the EDO and dividing by two. When the distance from the EDO was a half-day, it was rounded down to the next whole day. For example, day 0 was from -0.5 to +0.5, day +1 was from 1 to 1.5, day -1 from -1 to -1.5, day 2 was from 2 to 2.5, and so forth. Frequency distribution for length of cycle appeared to be slightly positively skewed. This is related to the 7.5 percent of cycles that were either less than twenty-five days or greater than thirty-five days. Of the 7.5 percent of cycles that were out of the parameter, 4.5 percent of the cycles were greater than forty days.

Results

Menstrual Cycle Data Sets

Of the 165 participants, twenty-four of the participants produced only one to two cycles. These participants and their menstrual cycles were eliminated to reduce the data set from 1,181 to 1,142 cycles. Another ten participants who were classified as either having long cycles (greater than thirty-five days) or short cycles (less than twenty-five days) were eliminated from the data set. This reduced the data set to 131 women and 1,093 cycles of data or 92.5 percent of the original 1,181. Eliminating cycles after the second cycle was outside of the SDM twenty-six to thirty-two day range reduced this data set further. This final data set included 762 cycles or 65.5 percent of the original 1,181. Table 1 shows a comparison of the original and reduced data sets.

Table 1 Menstrual cycle data set summary

		Proportion of menstrual cycles			
Data set # of cycles	Mean length and <i>SD</i>	<26 days	26-32 days	>32 days	% of cycles with days of fertile window outside of days 8-19
1,181*	29.0/3.6	164 (13.9%)	840 (71.2%)	176 (14.9%)	314 (26.6%)
1,093†	28.8/3.3	149 (13.6%)	802 (73.4%)	141 (12.9%)	278 (25.4%)
762‡	29.0/3.1	78 (10.2%)	591 (77.7%)	92 (12.1%)	172 (22.5%)

* Data set with all menstrual cycles regardless of length.

† Data set with participants that had three or more regular cycles (25–35 days).

‡ Data set with participants and cycles that met rules of the SDM.

The mean length of the 762 menstrual cycles that remained in the data set was twenty-nine days (median 29; *SD* = 3.1; range 21–47). The mean EDO was 16.5 (median 16; *SD* = 3.1; range 9–27), and the mean length of the luteal phase was 12.5 days (median 13; *SD* = 1.8; range 5–21). The mean length of menses was 5.8 days (median 6; *SD* = 1.3, range 2–12). There were 591 (77.7 percent) of the cycles that were between twenty-six and thirty-two days in length, 78 (or 10.2 percent) that were less than twenty-six days in length, and 92 cycles or 12.1 percent longer than thirty-two days in length.

Demographics

The average age of the 131 participants that generated the final data set of 762 menstrual cycles of data was 29.3 years (*SD* = 5.6; range 19–44). They had an average of 1.4 children (*SD* = 1.7; range 0–8), and each generated three to thirteen cycles of data with the mean being 5.2 cycles (*SD* = 3.2).

Research Questions

In what percentage of the menstrual cycles does the EDO fall within one to three days of the midpoint of the cycle?

For the final data of 762 menstrual cycles, 714 cycles (93.7 percent) had an identifiable EDO based on the fertility monitor peak. Of these 714 cycles, 48.6 percent of the EDOs were within one day of the midpoint of the cycle, 67.7 percent were within two days of the midpoint, and 80.8 percent within three days of the midpoint (see table 2). For those cycles that were between twenty-six and thirty-two days in length, the percent of EDOs that were within one day of the midpoint of the cycle was 51.3 percent, within two days 72.3 percent, and 86.2 percent within three days of the midpoint. For cycles shorter than twenty-six days the percent of EDOs within one, two, and three days midpoint were 73.0 percent, 91.6 percent, and 97.2 percent; and for those cycles longer than thirty-two days, 9.4 percent, 16.5 percent, and 31.8 percent. As can be seen in figure 1, the EDOs were skewed toward the right and more so as the length of the cycles increased. The EDO of the 714 cycles had a strong positive correlation with the length of the cycles ($r = 0.820$, $p < 0.01$).

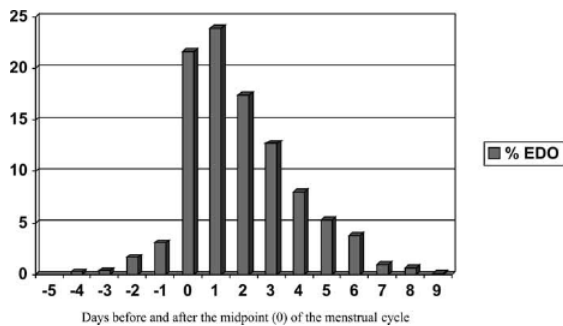


Figure 1 Percent frequency of where the estimated day of ovulation (EDO) falls in relation to the midpoint (0) of the menstrual cycle ($N = 714$).

Table 2 Percentage of menstrual cycles with the estimated day of ovulation (EDO) within one to three days of midpoint of cycle ($N = 714$ menstrual cycles)

	Proportion of menstrual cycles with EDO within		
Data set # of cycles	1 day of mid	2 days of mid	3 days of mid
Total 714	347 (48.6%)	483 (67.7%)	577 (80.8%)
72*	53 (73.0%)	66 (91.6%)	70 (97.2%)
557†	286 (51.3%)	403 (72.3%)	480 (86.2%)
85‡	8 (9.4%)	14 (16.5%)	27 (31.8%)

* Cycles in data set <26 days in length.

† Cycles in data set between 26 and 32 days in length.

‡ Cycles in data set >32 days in length.

In what percentage of menstrual cycles did the estimated fertile window fall outside of days eight to nineteen?

For the 714 cycles that had an EDO, 24 percent or 172 cycles had part of the estimated six-day fertile window outside of days 8 through 19 of the menstrual cycle (see table 3). For those cycles with lengths shorter than twenty-six days, approximately 45.8 percent (or thirty-three out of seventy-two) had part of the six-day window outside of days 8 through 19, for those cycles between twenty-six and thirty-two days in length, approximately 12.0 percent (or 67 of 557) had cycles with days of the fertile window outside of days 8 through 19, and for those cycles longer than thirty-six days, 83.5 percent (or seventy-one out of eighty-five) had cycles with part of the six-day fertile window outside of days 8 through 19. None of the short length cycles (i.e., less than twenty-six days in length) had days of estimated fertility after cycle day 19. Approximately 33 percent (twenty-two out of sixty-seven) of the cycles with lengths between twenty-six and thirty-two days had part of the six-day fertile window before days 8 through 19, and 67 percent (forty-five of sixty-seven) after. The longer cycles (greater than thirty-six days in length) only had days of the six-day fertile phase after day 19, but none before day 8.

Table 3 Percentage of menstrual cycles with days of estimated six-day fertile window (FW) before and after days eight to nineteen of the menstrual cycle

Data set # of cycles	Total before FW	Total after FW	Total outside FW
Total 714	55 (7.6%)	117 (16.4%)	172 (24.0%)

72*	33 (4.6%)	0 (00.0%)	33 (4.6%)
557†	22 (3.0%)	45 (6.3%)	67 (9.3%)
85‡	0 (00.0%)	72 (10.1%)	72 (10.1%)

* Cycles in data set <26 days in length.

† Cycles in data set between 26 and 32 days in length.

‡ Cycles in data set >32 days in length.

Only nine (16.4 percent) of the fifty-five cycles with part of the fertile window before days 8 through 19 had high fertility monitor readings (i.e., threshold levels of E3G present) on those days. These nine cycles were produced by eight (6.1 percent) of the 131 participants. Few (10 or 12.6 percent) of the estimated seventy-nine fertile window days that fell before day 8 had high (E3G) electronic fertility monitor recordings. Most (nine) of the high readings occurred on the day before the SDM eight to nineteen estimated days of fertility. The percentage of the fertile window days with high and peak readings that fell after day 19 would total close to 100 percent since the fertile window was based on the monitor second peak day and the monitor will automatically record two peak days preceded by days of high fertility. Finally, a review of cervical mucus of these cycles showed that only nineteen (34.5 percent) had cervical mucus present on fertile window days before days 8 through 19, but ninety-six (82.1 percent) had fertile mucus recorded on fertile window days after day 19.

Discussion

The findings in this study were computed using a fairly large data set of menstrual cycles that included biological parameters not usually found in data sets on menstrual cycles, including the day of the urinary LH surge, the length and peak in cervical mucus, and the first threshold high of urinary E3G. Results show a typical pattern of statistical parameters of the menstrual cycle, including mean length of cycles (i.e., twenty-nine days), mean length of the luteal phase (twelve days), length of menses (five days), and mean day of the EDO (day 16). These statistical parameters are similar to those in a recent study that investigated the length of 786 menstrual cycles produced by 130 participants and to those in the 1983 World Health Organization (WHO) five-country study of the ovulation method.¹⁴

The data set of regular cycles ($N = 762$) for this study had 77.7 percent of the cycles between twenty-six and thirty-two days. This is a similar percentage of menstrual cycles (with lengths between twenty-six and thirty-two days) that was found when applied retrospectively with the WHO (1983) data set (77.58 percent),¹⁵ less than that found with users screened for use of the SDM (90 percent),¹⁶ but more than the percentage (72 percent) that was found with users of a new simplified form of estimating fertility by cervical mucus observations called the TwoDay Method.¹⁷ These results make sense since the current study data set of (764 cycles) and the WHO data set had a similar screening range for regular cycles as compared to the more restrictive length for the SDM and less restrictive length for the TwoDay Method. Furthermore, users of the TwoDay Method were not screened for cycle regularity as users of the SDM would be.

Percentage of Cycles with EDO near Midpoint

The results showed that most (80.8 percent) of the menstrual cycles in the data set had an EDO within three days of the midpoint of the cycle. This percentage increased to 97.2 percent with shorter cycles

(i.e., those less than twenty-six days in length) and decreased to 31.8 percent with longer cycles (i.e., those greater than thirty-two days in length). Although most EDOs in the data set were within three days of the midpoint of the cycle, there was a shift to the right of the midpoint in the frequency of the EDOs (see figure 1), i.e., most of the EDOs (73 percent) fell three days after the midpoint of the cycle. There was a strong significant correlation of the EDOs with cycle length ($r = 0.820$, $P < 0.01$). This correlation indicates that the variability of the cycle length is due largely to variations in the follicular phase of the cycle and the process of ovulation.

Percent of Cycles with Fertile Window outside of Days 8 through 19

The results showed that 55 (7.7 percent) of the 714 menstrual cycles with an EDO had days of the fertile window before day 8, and 117 (16.4 percent) had days of the fertile window after days 8 through 19. There was a total of 172 (24.1 percent) days of the fertile window outside of days 8 through 19 of the menstrual cycle. The majority (seventy-one days or 90 percent of the total) of the fertile window days before cycle day 8 were one or two days before day 8. This means that most of the days that fell before day 8 were toward the beginning of the six-day fertile window (i.e., days 1 and 2 of the fertile window) and are the days with the lowest probability of pregnancy with a single act of intercourse.¹⁸ In contrast, the majority (75 percent) of the days of the fertile window that fell after day 19 fell within one to three days after. These days (i.e., days 4 to 6 of the fertile window) are days with the highest probability of pregnancy with a single act of intercourse. Therefore, these days would have the most impact on the effectiveness of the SDM.

The actual probability of pregnancy with a single act of intercourse should be reduced on those days of the fertile window that fall outside of days 8 through 19. This is also supported by the data that showed only 12.6 percent of the fertile window days that fell before day 8 had high fertility monitor readings (i.e., an indication of the rise in estrogen and the beginning of the actual fertile phase). However, these findings should be viewed with caution, since data from the WHO (1983) study showed that low quality self-observed cervical mucus days had a high probability of pregnancy when they fell close to the EDO.¹⁹ In addition, the high reading of the Clearblue Monitor often underestimates the beginning of the actual fertile phase.²⁰ However, we also found that 34.5 percent of the menstrual cycles analyzed did not have mucus present on estimated fertile window days and thus would be considered false negatives. This suggests the cervical mucus only methods have some of the same limitations in this regard. A large multisite cervical mucus only study in 1999 reported a use effectiveness rate at 99.5 percent and 96.8 percent for avoiding pregnancy that did have approximately 24 percent irregular length cycles that could also be used to compare the results of this descriptive analysis. However, this study does not report specific lengths of cycles nor the EDO to provide for another point of reference, and its standardization of pregnancies is multilevel. Therefore due to this method's unique analysis of pregnancies, it is not possible to compare to other methods of family planning.²¹ Finally, M.P. Stanford and J.B. Howard also provided an analysis of effectiveness for a cervical mucus only method. This study reported 701 couples of which 19.9 percent were in irregular cycles (i.e., long cycles less than thirty-eight days total, breastfeeding, and breastfeeding weaning). This study showed a net pregnancy rate of 18 to 24 per 100 couples.²² Although both of these cervical mucus studies do have a large number of irregular cycles reported, they did not provide sufficient statistics for this evaluation.

A limitation of this study is that the estimation of the day of ovulation (i.e., the EDO and the subsequent fertile window) is an estimation based on imperfect markers of fertility. The EDO was based on a threshold urinary LH surge determined with the Clearblue Fertility Monitor. A recent discussion of the LH surge has indicated that there is a high potential for false positives.²³ However, this high potential was based on urinary LH test kits with a fairly low threshold of urinary LH detection. This study did not utilize an LH test kit, but rather a fertility monitor that has a threshold test of E3G that precedes the LH surge. An independent study that utilized serial ultrasound of the developing follicle to determine the day of ovulation has shown that the ovulation fell within the two peak days of the monitor 91 percent of the time, and 97 percent on those two days and the day after.²⁴ Furthermore, the urinary LH surge correlates very close to the ultrasound estimated day of ovulation.²⁵ Evidence suggests that use of the monitor is an acceptable and accurate means to determine the EDO and the fertile phase.

Approximately 7 percent of the menstrual cycles in the data sets utilized for this study did not have an EDO, i.e., the monitor failed to detect a urinary LH surge. The percentage of cycles in the original 1,181 cycle data set that did not have an identified EDO was 7.4 percent, and for the final data set of 762 regular cycles, it was 6.2 percent. Whether those cycles that did not have an identifiable EDO were actually ovulatory and how their exclusion from the analysis affected the results is unknown. The percentage of cycles with a LH surge-related EDO increased with cycle lengths closer to the twenty-six to thirty-two day range.

The final data set (of 714 cycles), utilized for the analysis in this study, is a very conservative approximation of what might be found with use of the SDM. The menstrual cycles in the data set were generated by women who were screened to be in regular cycles that were defined as twenty-five to thirty-five days in length, a length that is more liberal than that used for the SDM. Furthermore, the screening procedures used for those entering the effectiveness study that produced this data set were less rigorous than those used for the SDM.²⁶ Better results would be obtained if participants for this study were screened specifically for use of the SDM. A prospective study that entered users of the Clearblue Fertility Monitor that have been screened for use of the SDM would be a more accurate evaluation of the SDM.

The implications that the results have for practice and use of the SDM is that the SDM is accurate in covering the six-day fertile window when cycles are between twenty-six and thirty-two days in length, and fairly robust when menstrual cycles are outside of that length range and parts of the fertile window are not covered by days 8 through 19. When the SDM fails to cover the beginning of the fertile window, the probabilities of pregnancy from a single act of intercourse are potentially very low. For example, the probability of pregnancy is 0.08 in the early days of the fertile window.²⁷ When it fails to cover the end of the fertile window, the probabilities are higher (closer to 0.35).²⁸ So when a user of the SDM has one or two cycles shorter than twenty-six days, she can feel secure in the method. One or two cycles longer than twenty-six to thirty-two days are more troublesome.

A major practical limitation of the SDM is that the method is not flexible enough to be effective with irregular menstrual cycles. However, the recent extended study of the SDM from five developing countries showed that the method did not apply to 2 to 3 percent of the participants (due to cycle irregularity) in the second year of use, down from 13 to 28 percent of participants in the first year of

use.²⁹ The developers of the method recognized the problem and have built into their instructions that the method does not apply when the woman has two cycles that fall out of their algorithm. Furthermore, they offer a simple mucus based method to meet this problem.³⁰ They also have developed a bridge method for postpartum breastfeeding women to help manage one of the most difficult transitions and source of irregular menstrual cycles.³¹

It should also be pointed out that most efficacy studies of natural methods of family planning include only women with regular menstrual cycles. Recognizing that the only way to determine comparable efficacy is through randomized comparison studies, probably the best comparison of efficacy to the SDM would be the five-country study of the ovulation method, which had a typical use pregnancy rate of 23 per 100 women over twelve months of use compared with the SDM.³² Furthermore, there is very little evidence of the efficacy of standard methods of NFP (i.e., mucus or mucus plus basal body temperature) with irregular cycles; and with the breastfeeding transition the unintended pregnancy rates are problematic and might even increase the rate compared with no method.³³

The SDM would capture a greater percentage of cycle lengths and reduce the probability of pregnancy by adding a day to the beginning and end of days 8 through 19 (i.e., days 7 through 20), but this would increase the required amount of avoidance of unprotected intercourse to two weeks. The SDM algorithm could also be modified to increase the recommended cycle lengths that it applies to or increase the number of cycles that could fall outside of the twenty-six to thirty-two day length in a given year. However, the current algorithm seems to be a good fit for variations in the menstrual cycle within individual cycle use and among a population of users. Other recommended research would be to use this data set to evaluate other calendar-based algorithms and mucus-based method algorithms including the TwoDay Method, which was recently developed at Georgetown University Institute for Reproductive Health.³⁴

Notes

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